## REMARKS

An Office Action was mailed in the above-captioned application on July 21, 2006. Claims 1-4, 8, 10-12, 14-15, 18-21, 23-25, and 35-37 were pending in the application. Claims 1-4, 8, 10-12, 14-15, 18-21, and 23-25 were withdrawn from consideration. Claims 35-37 were rejected. This Amendment and Remarks document is submitted in response to said Office Action. By the foregoing amendment, Claims 1-34 have been cancelled, Claim 35 has been amended and new claims 47-57 have been added. Support for the new claims can be found in Original Claims 38-46, and throughout the specification, including page 6, lines 21-23, and page 7, lines 15-18.

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 35-37 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity.

Specifically, the rejection indicates that the steps are confusing in that in step (h) of claim 35 it is allegedly unclear if the heavy layer from a potential second phase separated mixture is separated. The rejection further alleges that in step (h) "said heavy layer" appears to lack antecedent basis. Finally, the rejection alleges that the steps are confusing in that the claims fail to include a step which actually results in obtaining the lipid.

Claim 35 has been amended to recite, in step (g) that the step produces an additional phase separated mixture comprising an additional heavy layer and an additional light layer. Step (h) has been amended to recite the additional phase separated mixture and the additional heavy layer to clarify that step (h) refers to step (g). Claim 35 has also been amended to recite "whereby lipids are obtained from microorganisms" to clarify that the method results in obtaining lipids. In light of these amendments, applicant respectfully requests reconsideration of the rejection under 35 U.S.C. § 112, second paragraph.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 35-37 under 35 U.S.C. § 103(a) as being unpatentable over Gudin, et al., U.S. Pat. No. 5,179,012 in view of Wagner, et al., U.S. Patent No. 4,720,456. The Examiner bears the burden of establishing a prima facie case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

> whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success . . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

*In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Specifically, the rejection contends that Gudin, et al. teaches methods for obtaining liposoluble components from microorganisms, comprising culturing the microorganism in a medium, grinding the microorganism and separating the phases via centrifugation to obtain the desired components. The rejection further alleges that Gudin, et al., does not teach contacting the fermentation medium with a base, or wherein the temperatures are raised to at least 50°C, but that Wagner, et al., teaches methods for obtaining liposoluble components from microorganisms wherein the culture medium is adjusted with alkaline metal hydroxides and cultured at temperatures of 50°C, and that the addition of hydroxide increases the yield of lipids. The rejection reasons that it would have been obvious to culture microorganisms at about 50°C in the presence of hydroxides for the disclosed advantages of increased lipid yields.

It is respectfully submitted that Gudin, et al. does not disclose all the elements of independent Claim 35, and that Wagner, et al., does not remedy the deficiencies of Gudin, et al., Applicant therefore submits, as explained in detail below, that the combination of Gudin, et al., and Wagner, et al. can not render obvious Claims 35-37.

Claim 35 requires, in step d) separating substances of different densities from said lysed cell mixture to produce a phase separated mixture comprising a heavy layer and a light layer, wherein said heavy layer comprises an aqueous solution and said light layer comprises emulsified lipids. Gudin, et al., does not teach such a step. The phases that Gudin, et al., references are a liquid phase and a solid phase (col. 2, line 54). The liquid and solid phases are the result of the addition of a solvent, the function of which is to solubilize antioxidants produced

by the microorganisms. In the solvent extraction process described by Gudin, et al. (see column 2, lines 51-53; column 4, lines 3-21 and column 5, line 56-column 6, line 11), the desired product, antioxidants, preferentially migrate to the solvent phase and can subsequently be recovered. The presence of emulsified lipids in a light layer is not taught. The solid phase in Gudin, et al., contains the cellular debris. On the other hand, the present invention involves a straightforward density separation. The desired product, lipid, is efficiently and effectively separated from the fermentation broth based on density, e.g., by centrifugation. As a result, the cellular debris reside in the aqueous phase, rather than a solid phase, and the desired lipid product is in its own lipid-rich phase, rather than dissolved or dispersed in an added solvent phase. While the cellular debris in the solid phase of Gudin, et al., can be pelleted by centrifugation, such a centrifugation does not result in a phase phase separated mixture comprising a heavy layer and a light layer as required by the present invention.

Wagner, et al. does not remedy the deficiencies of Gudin, et al., since Wagner, et al., also does not teach or suggest separating substances of different densities from said lysed cell mixture to produce a phase separated mixture comprising a heavy layer and a light layer, wherein said heavy layer comprises an aqueous solution and said light layer comprises emulsified lipids. Thus, the teachings of Gudin, et al., and Wagner, et al., when taken together, do not teach or suggest separating substances of different densities from said lysed cell mixture to produce a phase separated mixture comprising a heavy layer and a light layer, wherein said heavy layer comprises an aqueous solution and said light layer comprises emulsified lipids, as required by Claim 35.

There are further specific differences between the present claims and the processes taught by Gudin, et al. and Wagner, et al.

Claim 35 requires in step b), contacting said fermentation broth with a base to dissolve at least a part of any proteins present in said fermentation broth. Wagner, et al. teaches the addition of alkaline metal hydroxides to maintain the pH of growing culture at a selected value (pH=3-8) in order to limit the source of nitrogen in the culture (col. 4, lines 29-30, and col. 5, lines 48-57). The present invention does not teach the addition of base to maintain the pH of a growing culture, but rather to dissolve protein, which interrupts the biochemical processes of the microorganisms. The addition of base in Wagner, et al., and the addition of base in the presently claimed invention are made for vastly different purposes. Wagner, et al., adjusts pH to promote

growth, while in the present invention the pH is raised with a base to dissolve proteins, which will slow or stop growth of the microorganisms.

Furthermore, the present invention teaches destruction of the proteins because the inventors identified them as a component responsible for maintaining the emulsion of oil and water that hinders recovery of the lipids. Gudin, et al., on the other hand, tries to recover the proteins. Gudin, et al., teaches recovery of SOD, an enzyme (protein) and therefore teaches conditions that protect proteins rather than those that denature or hydrolyze proteins. Thus, the teachings of Gudin, et al., and Wagner, et al., when taken together, do not teach or suggest contacting said fermentation broth with a base to dissolve at least a part of any proteins present in said fermentation broth, as required by step b) of Claim 35.

With regard to the rejection's statement that Wagner, et al. teaches culturing microorganisms at temperatures of 50°C, this teaching also does not obviate the present invention. Wagner, et al., teaches growth of microorganisms from 15°C to 50°C, or below 50°C (col. 4, lines 23-31). Thus, in Wagner, the temperature of 50°C represents an upper limit for the growth conditions of the microorganisms. In contrast, the present invention does not teach or require culturing microorganisms at 50°C; rather, Claim 35 requires increasing the temperature of said fermentation broth to at least about 50°C to lyse cells of said microorganisms to produce a lysed cell mixture. In other words, in the present invention, 50°C represents a lower limit for the temperature used to lyse, i.e., kill, the cells. Neither Wagner, et al., nor Gudin, et al. teach increasing the temperature of a microorganism fermentation broth to at least about 50°C to lyse the cells. Thus, the teachings of Gudin, et al., and Wagner, et al., when taken together, do not teach or suggest step c) of Claim 35.

For the foregoing reasons, Applicant submits that the combination of Gudin, et al., and Wagner, et al., cannot obviate the present invention and respectfully requests reconsideration of the rejection under 35 U.S.C. § 103.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

No fee is believed due with this submission; however, the undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: /Darla G. Yoerg/
Darla G. Yoerg
Registration No. 48,053
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

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